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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/929,852	08/14/2001	William H. Hildebrand	6680.025	9815

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EXAMINER

VANDERVEGT, FRANCOIS P

ART UNIT PAPER NUMBER

1644

DATE MAILED: 03/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/929,852

Applicant(s)

HILDEBRAND, WILLIAM H.

Examiner

F. Pierre VanderVegt

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 5-14 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 5-14 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: ____

DETAILED ACTION

The Examiner in charge of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to F. Pierre VanderVegt, Ph.D. in Art Unit 1644.

This application is a continuation of U.S. Application Serial Number 09/465,321.

Claims 3 and 4 have been canceled.

New claims 9-14 have been added.

Claims 1, 2 and 5-14 are currently pending and are the subject of examination in the present Office Action.

In view of Applicant's amendment filed December 5, 2003, all outstanding grounds of rejection are withdrawn.

The following new grounds of rejection have been necessitated by Applicant's amendment.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1, 2 and 5-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "large scale" in claims 1, 11 and 12 is a relative term that renders the claim indefinite. The term "large scale" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention. The term "large scale," when applied to production of a product carries the implication of making that product in industrially significant quantities at a rate not attained by the routiner. However, there is no guidance from the specification regarding what the metes and bounds of the term as applied to the present invention are. What may be "large scale" for one protein product may not be large scale for another. Does the term imply any quantity and rate of production that is accelerated versus a single culture flask, two flasks, one roller bottle or a 5-gallon fermenter? Without guidance regarding the metes and bounds of the term "large scale" it is not possible for the artisan to

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understand the amount of production that is encompassed by the claim. Accordingly, the use of the relative term "large scale" renders the claims ambiguous and indefinite.

The use of the phrase "production of large quantities" is not included in this ground of rejection because "large quantities" can be made by any production method, including "small scale" systems.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claims 1, 2 and 5-14 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,232,445 B1 to Rhode et al. (A on form PTO-892).

The '445 patent teaches a method for large-scale continuous production of large quantities of an individual MHC molecule. The '445 patent teaches the isolation of the total mRNA from a immortalized cell line source [claim 8] and reverse transcribing mRNA to form cDNA (column 47, lines 31-54 in particular). The '445 patent teaches PCR amplification of MHC molecules truncated to exclude the transmembrane and cytoplasmic domains (column 47, lines 31-54 in particular). The '445 patent teaches cloning the PCR product into a mammalian expression vector comprising a promoter [claim 7] (column 48, lines 55-67 and column 49, lines 1-3 in particular). The '445 patent further teaches that the soluble MHC molecule may comprises a tail or "tag," such as 6x-His that can be used for purification [claims 9 and 10] (column 27, lines 8-20 and column 54, lines 59-64). The '445 patent further teaches transfecting the mammalian expression vector into Chinese hamster ovary cells (column 53, lines 18-37 in particular) and inoculating hollow fiber bioreactors for large scale continuous production of soluble individual MHC molecules and that the bioreactors are continuously fed with fresh oxygenated medium [claim 2] and soluble MHC molecules are harvested continuously for 30-120 days [claim 5](column 53, lines 56-67 and column 54, lines 1-5 in particular). The '445 patent further teaches that other mammalian cell types can be used, including human-derived HeLa cells, a known non-MHC class I expressing cell line (column 29,

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5-11 in particular). While the examples recited in the '445 patent used MHC class II molecules for exemplification of the method, the '445 patent teaches that both MHC class II and MHC class I molecules are embraced by the practice of the method (column 2, lines 50-67 and column 3, lines 1-47 in particular). Furthermore, it is well within the purview of the artisan to obtain primers for practicing the method of the '445 patent and use them to amplify the extracellular domains of MHC class I in the same manner as the MHC class II molecule exemplifies. The prior art teaching anticipates the claimed invention.

Conclusion

3. No claim is allowed.
4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00; Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

F. Pierre VanderVegt, Ph.D.
Patent Examiner
March 3, 2004

PV

Pat J. Nolan
PATRICK J. NOLAN, PH.D.
PRIMARY EXAMINER
3/5/04